DETAILED ACTION

1. This Office Action is responsive to the amendment filed 3/2/2008. Claim 8 is new. **Claims 1-8** remain pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 3/2/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al (US Pat No. 6816744) in view of Borkan (US Pat No. 6662053), further in view of Fuchs (US Pat No. 5747996).

5. In regard to **Claims 1 and 8**, Garfield et al disclose an electromyogram (EMG) system comprising at least one EMG sensor (201-204) positioned three-dimensionally on a patient (Col. 28: 13-15) and best seen in Figure 12, operative to sense electromyographic activity generated in

a uterine muscle and output electrical muscular activity signals of said uterine muscle, best seen in Figure 5a and 8, and a processor (22), referred to as "computer," in communication with said EMG system, operative to process electrical muscular activity signals of said EMG system and along with other types of data, i.e. cardiac and brain activity (Col.8, line 20-30) as well as provide an output and display through monitor 23 of said electrical muscular activity signals as sensed by said at least one EMG sensor, best seen in Figure 3.

6. However, Garfield et al do not disclose at least one position sensor placed near said at least one EMG sensor and said processor in communication with said at least one position sensor to process three dimensional positions of said at least one EMG sensor from said at least one position sensor to provide an output and display of both said electrical muscular activity signals sensed by said at least one EMG sensor and the three dimensional positions of said at least one EMG sensor at the same time.

7. Borkan teaches that data from EMG sensors (Col.5: 1-22) aid in the determination the position of simulator electrodes, wherein the position is determined and displayed in conjunction with other pertinent data (Col.2: 30-33; Col.3: 1-14) as the result of processing by a processor 20 to ensure the proper positioning of the simulator electrodes for the desired application or use (Col.8: 52-57; Col.10: 9-21). However, Borkan does not explicitly disclose the position as three-dimensional and determined by a position sensor. Fuchs teaches a spatial position sensor 31, 32, 33 used to determine the position of another sensor, i.e. a magnetometer (Col.4: 19-21) relative to a reference element 6 as an effective device to determine the three dimensional position (Col.3: 26-28) of said sensor for medical purposes (Col.2: 26-27; Col.4: 10-18).

8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include at least one position sensor with the EMG system of Garfield et al and have the processor in communication with said EMG system and said at least one position sensor, said processor operative to process electrical muscular activity signals of said EMG system and three dimensional positions of said at least one EMG sensor from said at least one position sensor to provide an output and display of said electrical muscular activity signals as sensed by said at least one EMG sensor and the three dimensional positions of said at least one EMG sensor, as taught by Borkan and Fuchs collectively, to improve the device of Garfield et al by providing pertinent information indicating the three dimensional positions of said at least one EMG sensor 201-204 as placed on the patient when sensing electromyographic activity generated in the muscle and thus providing relevant information as to the position of the patient's uterine contraction for better monitoring purposes.

9. Furthermore, as Borkan disclose the display of the position information at the same time as other relevant information as explained above, it would have been obvious to one of ordinary skill in the art to have the processor of Garfield et al as modified by Borkan and Fuchs provide an output and display of said electrical muscular activity signals as sensed by said at least one EMG sensor and the three dimensional positions of said at least one EMG sensor at the same time, to impart the advantages of simultaneous relay of pertinent information to the patient and/or user for more efficient use and monitoring.

10. Although Garfield et al as modified by Borkan and Fuchs do not explicitly disclose placing the at least one position sensor near said at least one EMG sensor, it is obvious and well known to one of ordinary skill in the art that the sensing of the position of said at least EMG

sensor requires that said at least one position sensor be placed near said at least one EMG sensor and thus should be placed as such for proper position monitoring.

11. In regards to **Claim 2**, Garfield et al disclose an EMG system comprising of at least one EMG sensor (201-204) and at least one reference EMG sensor (205) adapted to sense electromyographic activity generated in a muscle of interest and in a reference muscle, respectively (Col.23, line 20-22).

12. In regards to **Claim 3**, Garfield et al disclose a monitor (23) coupled to the processor to display the processed information from the processor.

13. In regards to **Claim 4**, Fuchs discloses a position sensing system adapted to measure the three dimensional position and orientation of said at least one position sensor 31-33 with respect to a reference position 6 fixed in space.

14. In regards to **Claim 5**, Garfield et al disclose a fetal cardiac unit (403) and tocodynamometer (401) as standard clinical devices useable in conjunction with the invention (Figure 7). Such standard devices inherently comprise of sensors used to obtain the necessary data. Thus, the fetal heart rate (FHR) sensor and TOCO sensor disclosed by Garfield et al may be referred to collectively as a CTG monitor. These sensors are connected to the EMG system, which in turn, are connected to the previously mentioned processor.

15. In regards to **Claim 6**, the collective CTG system comprising of fetal heart rate and TOCO sensors are connected to said processor. Garfield et al disclose sensors (17), such as those for fetal heart rate and TOCO of the collective CTG monitor, connected to the processor or

"computer" (22) in Figure 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have said processor of Garfield et al as modified by Borkan and Fuchs operative to process data from said CTG monitor in addition to the data of said EMG system and the three dimensional position information from said at least one position sensor, as explained above, to provide an output and display of electromyographic activity data and CTG data and the three dimensional position of said at least one MEG sensor *at the same time*, for the purpose of advantageously relaying pertinent information simultaneously to the patient and/or user for more effective monitoring and use.

16. In regards to **Claim 7**, Garfield et al disclose a warning mechanism in communication with the processor, operative to issue a warning if the processed data processed by said processor is above a predefined limit, or other abnormalities, are found (Col.16, line 26-28).

Response to Arguments

17. Applicant's arguments filed 3/2/2008 have been fully considered but they are not persuasive. Applicant contends that Borkan does not teach displaying the position of the simulator electrodes in conjunction with other pertinent data. However, as previously discussed, it is maintained that Borkan discloses that "the display may show overlays of an image of the desired electrode position and/or movement on an x-ray or fluoroscopic image." (Col.3: 1-14 and Col.5: 10-21). The electrode position is thus displayed in conjunction with an x-ray or fluoroscopic image, which constitutes pertinent data. Furthermore, the prior art is replete is examples of displays that show multiple types of data, which includes position data along with other types of data. For example, Varghese et al (US Pat No. 20040210136) discloses a system

for monitoring cervical and uterine data wherein the display shows multiple types of data in conjunction with each other, best seen in Figure 5.

18. It is also noted that all the claimed elements were known in the prior art and one of ordinary skill in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded a reasonable expectation of success. The only difference is the combination of the elements into a single device. Therefore, it would have been obvious one skilled in the art to provide a display of the electrical muscular activity signals and the three-dimensional positions of the at least one EMG sensor at the same time is to advantageously show multiple types of data.

19. It is also noted that while Applicant discusses a novel application of the simultaneous display of the electrical muscular activity signals and the three-dimensional positions of the EMG sensor to predict whether pre-term labor turns into pre-term or full-term delivery, such limitations have not been claimed. Thus, it is maintained that the combination of displaying electrical muscular activity signals at the same time with the three-dimensional positions of the EMG sensor is nonobvious in view of the references above and for the above elaborated reasons.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736